

## **ATTACHMENT 9**

No. GV002327

THE STATE OF TEXAS	:	IN THE DISTRICT COURT
	:	
<i>ex rel.</i>	:	
VEN-A-CARE OF THE	:	
FLORIDA KEYS, INC.	:	
	:	TRAVIS COUNTY, TEXAS
<i>Plaintiffs,</i>	:	
	:	
v.	:	
	:	
DEY, INC., DEY, L.P., A LIMITED	:	
PARTNERSHIP	:	
ROXANE LABORATORIES, INC.,	:	
WARRICK PHARMACEUTICALS	:	
CORPORATION, SCHERING PLOUGH	:	
CORPORATION, SCHERING	:	
CORPORATION, MERCK SANTE S.A.S.	:	
(F/K/A LIPHA, S.A.), MERCK S.A. (F/K/A	:	
MERCK-LIPHA, S.A.), MERCK KGaA,	:	
and EMD, INC.,	:	
	:	53 <sup>RD</sup> JUDICIAL DISTRICT
<i>Defendants.</i>	:	

**SETTLEMENT AGREEMENT AND RELEASE**

**Part I: Parties**

This Settlement Agreement (the "Agreement") is entered into by and between the STATE of TEXAS ("STATE"), Ven-a-Care of the Florida Keys, Inc. ("Relator"), (collectively referred to as "Plaintiffs"); and DEY, L.P. and DEY, INC. (collectively

June 3, 2003 (5:35pm)

referred to as "DEY") (the Plaintiffs and DEY shall be collectively referred to as the "Parties"), through their authorized representatives.

## **Part II: Preamble**

As a preamble to this Agreement, the Parties agree to the following:

A. DEY, INC. is a corporation organized under the laws of Delaware. DEY, L.P. is a limited partnership organized under the laws of the State of Delaware, and is owned by DEY, INC. and DEY Limited Partner, Inc. DEY L.P.'s headquarters are in Napa, California. DEY manufactures and sells certain pharmaceutical products. All references to DEY's "Affiliates" herein shall be deemed to include, without limitation, Merck KGaA, Merck Sante S.A.S., Merck S.A., EMD Pharmaceuticals, Inc. and EMD, Inc. (collectively, the "MERCK COMPANIES").

B. Plaintiffs contend that the STATE has civil claims against DEY under the Texas Medicaid Fraud Prevention Act, TEX. HUM. RES. CODE ANN. chapter 36, and under common law for unlawful actions taken by DEY through the date this Agreement is executed, pertaining to the inclusion by DEY of certain drugs on the Texas Drug Code Index ("TDCI"). DEY's drugs that are covered under this Settlement are collectively referred to hereafter as the Covered Drugs, and are listed on **Exhibit A**, attached hereto and incorporated herein for all purposes. Specifically, Plaintiffs contend that DEY has committed unlawful acts, as defined by Tex. Hum. Res. Code Ann. § 36.002, in

conjunction with its submission of pricing information to the Texas Vendor Drug Program (“VDP”) for the purpose of including certain of DEY’s Covered Drugs on the TDCI. The acts and omissions sued upon and which are subject to the release language in this Agreement are set forth in Cause No. GV002327, *State of Texas, ex. rel. Ven-A-Care of the Florida Keys, Inc., vs. Dey, Inc., et.al.*, (the “Lawsuit”), and are alleged in the SIXTH AMENDED PETITION filed in the Lawsuit on or about April 11, 2003.

C. DEY's (and the Merck Companies') alleged conduct and transactions referenced in Paragraph II(B) are hereinafter referred to as the “Covered Conduct.” The Covered Conduct is expressly limited to: (i) conduct which has occurred prior to the date of the execution of this Agreement; and (ii) conduct as expressly alleged in the SIXTH AMENDED PETITION in the Lawsuit as though such conduct had been alleged with respect to all of the Covered Drugs. At the time of the execution of this Agreement, the Office of the Attorney General of Texas represents to DEY that it is not aware of any other filed *qui tam* lawsuit against the released parties under the Texas Medicaid Fraud Prevention Act.

D. DEY denies all of the Plaintiffs' claims and allegations and denies that it has any liability relating to such claims and allegations. DEY has asserted various defenses to the Plaintiffs' claims.

E. In order to avoid the delay, uncertainty, inconvenience and expense of protracted litigation of these claims, and as a result of a mutual desire to settle their

disputes, the Parties have reached a full and final settlement as set forth in this Agreement.

F. This Agreement does not constitute an admission of fault or liability by DEY or any of its Affiliates, nor does it constitute evidence of any liability or unlawful conduct on the part of DEY or any of its Affiliates, and the Plaintiffs will not urge or seek to admit this Agreement as evidence of any fault or liability of DEY or any of its Affiliates in any investigation, administrative proceeding, or federal or state court or arbitration proceeding.

G. Plaintiffs represent to DEY, subject only to the Relator's rights as a *qui tam* plaintiff under applicable state and federal law to participate in this Agreement and to receive a percentage of the Settlement Amount, and to the rights possessed by the United States, that no interest in any claim herein released has been assigned by them to any third party.

H. The STATE has concluded that this settlement is in the public interest.

I. Concurrent with this Agreement, DEY is entering into a separate release agreement with the United States of America regarding the Covered Conduct in the STATE. DEY's agreement with the United States of America is attached hereto and incorporated herein for all purposes as **Exhibit B**. The use of capitalized terms in the agreement attached as **Exhibit B** shall refer to and have the same meaning as the identical terms defined herein, unless otherwise expressly defined in **Exhibit B**.

**Part III: Terms and Conditions**

NOW, THEREFORE, in consideration of the mutual promises, covenants, and obligations set forth below, and for good and valuable consideration as stated herein, the Parties agree as follows:

**Incorporation of Representations**

- 1) The foregoing Preamble is incorporated herein.

**The Settlement Payment**

- 2) (a) DEY agrees to pay the STATE, the Relator, and the United States of America the collective sum of eighteen million five hundred thousand dollars (\$18,500,000) (the "Settlement Amount") in full payment of restitution and compensatory damages related to the Covered Conduct. DEY shall make payment of the Settlement Amount by check or wire transfer as follows:

- (1) The amount of \$1,131,500 payable to the State of Texas for the STATE's attorneys' fees and costs;

- (2) The amount of \$1,131,500 for the Relator's attorneys' fees and costs;

- (3) The amount of \$5,624,000 payable to the State of Texas, for the STATE's share;

- (4) The amount of \$1,406,000 for the Relator's share; and

(5) The amount of \$9,207,000 for the share due the United States of

America in accordance with the agreement attached hereto as **Exhibit B**.

(b) The payment for the Relator's attorneys' fees and costs and for the Relator's share shall be distributed in accordance with instructions delivered by Relator's counsel, James J. Breen to counsel for DEY. The payment for the STATE's attorneys' fees and costs and the STATE's share shall be delivered in accordance with instructions from Patrick J. O'Connell, Chief, Civil Medicaid Fraud Section, at the Office of the Attorney General of Texas. The payment for the United States' share shall be made in accordance with instructions delivered to DEY by counsel for the United States' Department of Justice. In the event payments are made by wire transfer the Parties will cooperate to exchange wiring and routing instructions so that such payments can be promptly made. The Relator will indemnify and hold DEY (and its Affiliates, including the Merck Companies) harmless from and against any and all claims for attorneys fees asserted by persons or entities who have represented the Relator in connection with the claims released herein.

**Plaintiffs: Release of DEY**

3) Subject to the exceptions in Paragraph III(8) below, in consideration of the obligations of DEY set forth in this Agreement, and conditioned upon DEY's payment in full of the Settlement Amount specified herein, the STATE (on behalf of itself, its officers, agents, agencies and departments), and the Relator (on behalf of itself and its

counsel) fully and finally release DEY, its parent corporation(s), subsidiaries and Affiliates (including without limitation each of the MERCK COMPANIES), their predecessors, successors and assigns as well as their respective current and former directors, officers, employees, agents, shareholders and attorneys (collectively, the “DEY Released Parties”) from any civil or administrative claim, action, suit or proceeding (including attorneys fees, costs, and expenses of every kind and however denominated) the STATE and Relator have or may have or could assert in the future under any source of law for the Covered Conduct. The payment of this Settlement Amount fully discharges DEY from any civil or administrative obligation to the STATE for the Covered Conduct. The Office of the Attorney General of Texas shall not initiate or prosecute litigation against DEY or the Merck Companies on behalf of the United States based on the Covered Conduct.

4) In consideration of the obligations of DEY set forth in this Agreement, conditioned upon DEY’s payment in full of the Settlement Amount specified herein, the STATE agrees to release and refrain from instituting, directing or maintaining any action seeking exclusion from the VDP or any other Texas Medicaid program against DEY, its parent corporation(s), subsidiaries and Affiliates (including without limitation each of the MERCK COMPANIES) their predecessors, successors and assigns for the Covered Conduct as it relates to the Texas Medicaid program, except as reserved in Paragraph III(8), below.



**Merck Companies Not Parties to Action**

5) Notwithstanding the foregoing, it is acknowledged that the MERCK COMPANIES have not appeared in the Action, are not parties to this Agreement and they shall not be deemed to have invoked the benefit of Texas laws, or the privilege of doing business in Texas, or otherwise to have submitted to jurisdiction in Texas or any other forum within the United States for any purpose by reason of being identified as intended beneficiaries of this Agreement.

**DEY: Release of the STATE and the Relator**

6) DEY fully and finally releases the STATE, its agencies, employees, servants, attorneys and agents from any claims based on events occurring prior to the date of this Agreement (including attorneys fees, costs, and expenses of every kind and however denominated) which DEY has asserted, could have asserted, or may assert in the future against the STATE, its agencies, employees, servants, attorneys and agents, related to the Covered Conduct and the Plaintiffs' investigation and prosecution thereof. This release shall not release any accounts receivable unrelated to the Covered Conduct due from the STATE, or any agency or instrumentality of the STATE.

7) DEY fully and finally releases the Relator, its employees, servants, attorneys and agents from any claims based on events occurring prior to the date of this Agreement (including attorneys fees, costs, and expenses of every kind and however denominated) which DEY has asserted, could have asserted, or may assert in the future against the

Relator, its employees, servants, attorneys and agents, related to the Covered Conduct and the Plaintiffs' investigation and prosecution thereof. This provision is not intended to release claims unrelated to conduct in Texas.

**Limitations on Release**

8) Notwithstanding any other terms of this Agreement, including the release provisions in paragraphs III(3) and (4) above, specifically reserved and excluded from the scope and terms of this Agreement, and from the scope and terms of the releases, as to any entity or person (including DEY), are any and all of the following:

- (a) Any claims based upon such obligations as are created by this Agreement;
- (b) Any express or implied product or service warranty claims or other claims for defective or deficient products or services, including quality of goods and services, provided by DEY;
- (c) The subrogation rights to claims for personal injury or property damage arising from usage by a participant in the Medicaid program of any of the Covered Drugs;
- (d) Any claims based on a failure to deliver products or services due;
- (e) Any claims arising from DEY's obligations to report and/or to pay rebates to the STATE under any law or contract;
- (f) Any claims that the Relator may have under any provision of 31 U.S.C.A. §§ 3729-3733 (the federal False Claims Act), excluding any claim related to

any recovery attributable to the impact on Texas Medicaid of the Covered Conduct; or

- (g) Any claims that the Relator may have under the *qui tam* provisions of the laws of any state other than Texas.

**Corporate Integrity Agreement**

9) Should DEY enter into a Corporate Integrity Agreement with the Office of the Inspector General of the United States Department of Health and Human Services (“OIG”), relating to the Covered Conduct, DEY acknowledges that the OIG may share information provided under the Corporate Integrity Agreement with the STATE.

**DEY’s Obligation to Report AMP to VDP**

- 10) DEY shall comply with the following:
  - (a) Within thirty days after the last day of each calendar quarter, DEY shall report to the VDP, in accordance with sub-paragraph (b) below, the average manufacturer’s price (“AMP”) of each of its drugs and pharmaceutical products (identified by DEY’S NDC codes) that are or shall be reimbursed by the VDP.
  - (b) The price reported by DEY with respect to each dosage form, strength and volume of the drug or pharmaceutical product (without regard to any special packaging, labeling, or identifiers on the dosage form or product or package), shall be the AMP as defined by the Omnibus Budget

Reconciliation Act of 1990, 42 U.S.C.A. § 1396r-8(k)(1), as amended.

Notwithstanding the foregoing, to the extent that any change in federal law releases DEY from any other obligation to report AMP to any other governmental agency for any other purpose, DEY shall continue to report AMP in accordance with this Agreement subject to subparagraph (e) below.

- (c) Confirmation Requirement: Concurrent with its report of AMP information to the STATE for the second quarter of 2003, DEY will furnish to the STATE DEY's description of the methodology that it uses to compute AMP on DEY's drugs listed on the TDCL. Thereafter, with each report of AMP information that DEY sends to the VDP, DEY shall also provide a description of each change in the methodology used to calculate the AMP for such drugs. An authorized agent of DEY shall certify that the AMPs reported to the VDP have been calculated in accordance with the described methodology to the best of the agent's knowledge and belief. Furthermore, an independent third party auditor selected by DEY shall confirm annually, commencing not later than April 30, 2004 and thereafter by April 30 of each succeeding year, that during the preceding calendar year the described methodology has been applied consistently in all material respects.
- (d) It is understood that DEY considers the AMP information, the methodology by which it is calculated, and the auditor's confirmation to be confidential

commercial information and proprietary trade secrets that if disclosed would cause substantial injury to the competitive position of DEY. It is further understood, however, that all information provided by DEY to the VDP pursuant to this Agreement shall be made available to the Office of the Attorney General of Texas upon request. Subject to the requirements of the Texas Public Information Act, all such price information and methodologies reported by DEY shall be treated as confidential by the VDP and shall not be disclosed by the VDP or its counsel to any other person or entity, except as otherwise provided by law. The STATE acknowledges that DEY contends that such information falls within the provisions of § 552.110(b) of the Texas Public Information Act.

- (e) DEY agrees to submit AMP information to the VDP in accordance with this paragraph for a period of seven years from the Effective Date of this Agreement.
- (f) DEY shall retain documentation supporting the calculation of AMP of its drugs for six years after the date of each certification and will make such documentation available for inspection by the VDP and the Office of the Attorney General of Texas.

**Safe Harbor**

11) DEY shall report (i) its AMP, in accordance with paragraph 10 above, for each DEY product listed on the TDCI and (ii) the pricing information required on the VDP questionnaire, as it presently exists, or as it may be amended in the future. In lieu of one price, DEY may report a range of prices for each category on the VDP questionnaire.

The VDP may derive DEY's WEAC from DEY's reported price information, in accordance with current VDP practice. Subject to the requirements of the Texas Public Information Act, all such price information reported by DEY shall be treated as confidential by the VDP and shall not be disclosed by the VDP or its counsel to any other person or entity, except as otherwise provided by law. For the duration of the AMP reporting period defined in paragraph 10(e) of this Agreement, the STATE covenants that, provided that DEY reports to VDP its AMP information in accordance with paragraph 10 of this Agreement, the STATE and the Relator will not sue, and will not seek to hold DEY liable under any law or regulation, for falsely reporting its other prices on the VDP questionnaire during such reporting period. This paragraph shall apply to all current and future DEY products listed on the VDP formulary.

**No Waiver or Release of Claims Against Other Persons**

12) This Agreement is intended to be solely for the benefit of the Parties and persons and entities released (including those released in **Exhibit B** attached), and except as stated herein, the Parties do not by this instrument release any claims against any other person or

entity, including any individual or entity that purchased drugs or pharmaceutical products from DEY. No word, term, phrase or definition in this Agreement is or may be used for the benefit of any person, entity or litigant who is not a signatory to, or released by this Agreement.

**Claims for Physician Services and Medicare**

13) The STATE and the Relator covenant not to sue DEY for claims relating to reimbursement by Texas Medicaid for the Covered Drugs: (i) administered by physicians or incident to physicians' services based upon any conduct, including the reporting of average wholesale price ("AWP") to national data reporting services; or (ii) for co-payments made under Medicare Part B, occurring prior to the date of this Agreement. Nothing in this paragraph or this Agreement shall waive, release or limit the STATE's or Relator's right to recover their share of proceeds from any judgment or settlement resulting from any claim under the Federal False Claims Act relating to such reimbursement.

**Dismissal of Action**

14) Simultaneously with the execution of this Agreement and payment of the Settlement Amount, the STATE and the Relator will execute agreed motion(s) to dismiss and agreed order(s) (in the forms collectively attached hereto as **Exhibit C**) dismissing with prejudice any lawsuit (including the Lawsuit) against DEY and/or the Merck Companies based on the Covered Conduct, but only as to DEY and the Merck

Companies. The STATE and Relator agree that they will not oppose a motion by DEY to vacate that certain Order Granting Sanctions against DEY, INC. and Robert Francis Mozak, dated January 8, 2003. The dismissal order in the Lawsuit shall provide that the Amended Protective Order entered in the Lawsuit shall remain enforceable in accordance with its terms, as same may be modified pursuant to paragraph 14 thereof.

**No Impairment or Creation of Rights**

15) Nothing in this Agreement shall be construed to abrogate or alter any future obligation of DEY pursuant to the law of the STATE.

**No Waiver of Sovereign Immunity**

16) Nothing in this Agreement shall be construed to create a waiver of the STATE's Sovereign Immunity.

**Mediation**

17) In the event disputes arise between the Plaintiffs and DEY in connection with the performance of this Agreement, the Parties shall promptly enlist the mediation services of Dean Kilgore to seek an amicable resolution of the disputes.

**Exclusive Venue for Enforcement of Agreement**

18) Either party shall be entitled to enforce the terms of this Agreement in the District Courts of Travis County, Texas, which shall have exclusive jurisdiction and venue over any such action.



**Complete Agreement**

19) This Agreement, including all exhibits, constitutes the complete agreement between the Parties and may not be amended except by written consent of the Parties.

**Costs**

20) Except as otherwise provided herein, each Party to this Agreement will bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

**Choice of Law**

21) This Agreement is governed by the laws of the State of Texas, except to the extent otherwise governed by federal law.

**Notification**

22) Unless otherwise stated in writing subsequent to the Effective Date of this Agreement, all notifications and communications made pursuant to this Agreement shall be submitted to the entities listed below:

(a) STATE :

(1) FOR SUBMISSION OF DATA:

TEXAS HEALTH & HUMAN SERVICES COMMISSION  
Bureau of Vendor Drugs  
Attn: Martha McNeill  
Mail Code Y915  
1100 W. 49<sup>th</sup> St.  
Austin, Texas 78756-3174

(2) FOR LEGAL NOTICES AND ALL OTHER PURPOSES:

OFFICE OF THE ATTORNEY GENERAL  
Civil Medicaid Fraud Section  
Elder Law and Public Health Division  
P O Box 12548  
Austin, Texas 78711-2548

(b) RELATOR for all purposes:

James J. Breen, Esq.  
The Breen Law Firm, P.A.  
3562 Old Milton Parkway  
Alpharetta, GA 30005

(c) DEY, INC. and DEY L.P. for all purposes:

John M. Kling, Esq., Senior Vice President, Legal  
DEY, L.P.  
2751 Napa Valley Corporate Drive  
Napa, California 94558

Steven A. Fleckman, Esq.  
Fleckman & McGlynn, PLLC  
Bank of America Tower  
515 Congress Avenue, Suite 1800  
Austin, Texas 78701-3503

**DEY: No Duress**

23) DEY represents that this Agreement is freely and voluntarily entered into without any degree of duress or compulsion whatsoever.

**Relator: Agreement Reasonable**

24) The Relator agrees that this Agreement is fair, adequate, and reasonable.

**Authorization**

25) The Parties have read the foregoing Agreement and accept and agree to the provisions contained herein and hereby have caused this Agreement to be signed as of the day and date adjacent to their respective signatures. The undersigned individuals signing this Agreement on behalf of DEY represent and warrant that they are authorized by DEY to execute this Agreement. The undersigned STATE signatories represent that they are signing this Agreement in their official capacities and that they are authorized to execute this Agreement. The undersigned Relator's signatory represents that he is duly authorized to sign this Agreement on behalf of the Relator.

**Counterparts**

26) This Agreement may be executed in counterparts, each of which shall constitute an original and all of which shall be deemed to constitute one and the same Agreement.

**Acts Necessary to Effectuate Agreement**

27) Each Party agrees to perform such further acts and to execute and to deliver such further documents as may reasonably be necessary to carry out this Agreement.

**Captions Are for Convenience Only**

28) The bold-face paragraph captions in this Agreement are for convenience only and do not add to, detract from or change the substantive language or terms of this Agreement.

**Effective Date**

29) The Effective Date of this Agreement shall be the date upon which all of the Parties below have executed this Agreement.

STATE of TEXAS  
Office of the Attorney General

DEY, INC. and  
DEY L.P.

By: \_\_\_\_\_

By: \_\_\_\_\_

Date: \_\_\_\_\_

Date: \_\_\_\_\_

Jeffrey S. Boyd  
Deputy Attorney General for Litigation  
Office of the Attorney General of Texas  
P.O. Box 12548  
Austin, Texas 78711-2548

Printed Name: \_\_\_\_\_

Title: \_\_\_\_\_

Texas Health & Human Services  
Commission

By: Albert Hawkins

Date: 6-10-03

Printed Name: Albert Hawkins

Title: Commissioner

Relator, Ven-a-Care of the Florida Keys,  
Inc.

Relator, Ven-a-Care of the Florida Keys,  
Inc.

By: \_\_\_\_\_

By: Zachary Bentley

Date: \_\_\_\_\_

Date: 6/10/03

James J. Breen, Esq.  
The Breen Law Firm, P.A.  
3562 Old Milton Parkway  
Alpharetta, GA 30005

Zachary Bentley

Title: President & Chairman

STATE of TEXAS  
Office of the Attorney General

DEY, INC. and  
DEY L.P.

By: \_\_\_\_\_

By: \_\_\_\_\_

Date: \_\_\_\_\_

Date: \_\_\_\_\_

Jeffrey S. Boyd  
Deputy Attorney General for Litigation  
Office of the Attorney General of Texas  
P.O. Box 12548  
Austin, Texas 78711-2548

Printed Name: \_\_\_\_\_

Title: \_\_\_\_\_

Texas Health & Human Services  
Commission

By: Albert Hawkins

Date: 6-10-03

Printed Name: Albert Hawkins

Title: Commissioner

Relator, Ven-a-Care of the Florida Keys,  
Inc.

Relator, Ven-a-Care of the Florida Keys,  
Inc.

By: \_\_\_\_\_

By: \_\_\_\_\_

Date: \_\_\_\_\_

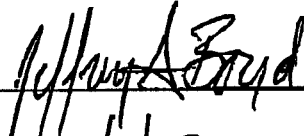
Date: \_\_\_\_\_

James J. Breen, Esq.  
The Breen Law Firm, P.A.  
3562 Old Milton Parkway  
Alpharetta, GA 30005

Zachary Bentley

Title: \_\_\_\_\_

**STATE of TEXAS**  
**Office of the Attorney General**

By:   
Date: 6/4/03

Jeffrey S. Boyd  
Deputy Attorney General for Litigation  
Office of the Attorney General of Texas  
P.O. Box 12548  
Austin, Texas 78711-2548

**DEY, INC. and**  
**DEY L.P.**

By: \_\_\_\_\_

Date: \_\_\_\_\_

Printed Name: \_\_\_\_\_

Title: \_\_\_\_\_

**Texas Health & Human Services**  
**Commission**

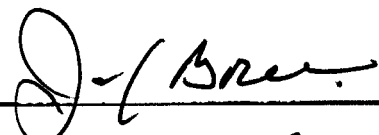
By: \_\_\_\_\_

Date: \_\_\_\_\_

Printed Name: \_\_\_\_\_

Title: \_\_\_\_\_

**Relator, Ven-a-Care of the Florida**  
**Keys, Inc.**

By:   
Date: 6-9-03

James J. Breen, Esq.  
The Breen Law Firm, P.A.  
3562 Old Milton Parkway  
Alpharetta, GA 30005

**Relator, Ven-a-Care of the Florida**  
**Keys, Inc.**

By: \_\_\_\_\_

Date: \_\_\_\_\_

Zachary Bentley

Title: \_\_\_\_\_

**STATE of TEXAS**  
**Office of the Attorney General**

By: Jeffrey S. Boyd  
Date: 6/4/03

Jeffrey S. Boyd  
Deputy Attorney General for Litigation  
Office of the Attorney General of Texas  
P.O. Box 12548  
Austin, Texas 78711-2548

**DEY, INC. and**  
**DEY L.P.**

By: \_\_\_\_\_

Date: \_\_\_\_\_

Printed Name: \_\_\_\_\_

Title: \_\_\_\_\_

**Texas Health & Human Services**  
**Commission**

By: \_\_\_\_\_

Date: \_\_\_\_\_

Printed Name: \_\_\_\_\_

Title: \_\_\_\_\_

**Relator, Ven-a-Care of the Florida**  
**Keys, Inc.**

By: \_\_\_\_\_

Date: \_\_\_\_\_

James J. Breen, Esq.  
The Breen Law Firm, P.A.  
3562 Old Milton Parkway  
Alpharetta, GA 30005

**Relator, Ven-a-Care of the Florida**  
**Keys, Inc.**

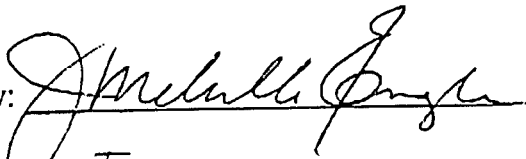
By: \_\_\_\_\_

Date: \_\_\_\_\_

Zachary Bentley

Title: \_\_\_\_\_



<p><b>STATE of TEXAS</b>  <b>Office of the Attorney General</b></p> <p>By: _____</p> <p>Date: _____</p> <p>Jeffrey S. Boyd          Deputy Attorney General for Litigation          Office of the Attorney General of Texas          P.O. Box 12548          Austin, Texas 78711-2548</p>	<p><b>DEY, INC. and</b>  <b>DEY L.P.</b></p> <p>By: <u></u></p> <p>Date: <u>JUNE 11, 2003</u></p> <p>Printed Name: <u>J. MELVILLE ENGLE</u></p> <p>Title: <u>PRESIDENT AND C.E.O.</u></p>
<p><b>Texas Health &amp; Human Services</b>  <b>Commission</b></p> <p>By: _____</p> <p>Date: _____</p> <p>Printed Name: _____</p> <p>Title: _____</p>	
<p><b>Relator, Ven-a-Care of the Florida</b>  <b>Keys, Inc.</b></p> <p>By: _____</p> <p>Date: _____</p> <p>James J. Breen, Esq.          The Breen Law Firm, P.A.          3562 Old Milton Parkway          Alpharetta, GA 30005</p>	<p><b>Relator, Ven-a-Care of the Florida</b>  <b>Keys, Inc.</b></p> <p>By: _____</p> <p>Date: _____</p> <p>Zachary Bentley</p> <p>Title: _____</p>

**EXHIBIT "A"**  
**COVERED DRUGS**

Dey	Albuterol Sulfate Inhalation Solution .083% 3ml	25	49502-0697-03
Dey	Albuterol Sulfate Inhalation Solution .083% 3ml	30	49502-0697-33
Dey	Albuterol Sulfate Inhalation Solution .083% 3 ml	60	49502-0697-60
Dey	Albuterol Sulfate Concentrate Solution 0.5% 20 ml	1	49502-0105-01 49502-0196-20
Dey	Acetylcysteine Solution 10% 4 ml	12	49502-0181-04
Dey	Acetylcysteine Solution 10% 10 ml	3	49502-0181-10
Dey	Acetylcysteine Solution 10% 30ml	3	49502-0181-30
Dey	Acetylcysteine Solution 20% 4 ml	12	49502-0182-04
Dey	Acetylcysteine Solution 20% 10 ml	3	49502-0182-10
Dey	Acetylcysteine Solution 20% 30 ml	3	49502-0182-30
Dey	Acetylcysteine Solution 20% 100 ml	1	49502-0182-00
Dey	Cromolyn Sodium Inhalation Solution USP 20mg 2ml	60	49502-0689-02
Dey	Cromolyn Sodium Inhalation Solution USP 20mg 2ml	120	49502-0689-12
Dey	Ipratropium Bromide 0.02% 2.5ml	25	49502-0685-03
Dey	Ipratropium Bromide 0.02% 2.5ml	30	49502-0685-33
Dey	Ipratropium Bromide 0.02% 2.5ml	60	49502-0685-60
Dey	Albuterol Aerosol Inhaler Kit 90mcg 17 gm	1	49502-0333-17 49502-0303-17

Dey	Albuterol Aerosol Inhaler Refill 90mcg 17 gm	1	49502-0303-27 49502-0333-27
Dey	AccuNeb® (albuterol sulfate) Inhalation Solution 0.63 mg 3 ml	25	49502-0692-03
Dey	AccuNeb® (albuterol sulfate) Inhalation Solution 1.25 mg 3 ml	25	49502-0693-03

Dey	Ace® Holding Chamber	1	49502-0203-01 49502-3080-10
Dey	Ace® Holding Chamber Hospital Pack	25	49502-3080-25
Dey	Ace® Plastic Adapters	5	49502-3080-60
Dey	Astech® Peak Flow Meter	1	49502-0200-01 49502-3070-10
Dey	Astech® Peak Flow Meter Hospital Pack	25	49502-0200-99 49502-3070-25
Dey	Astech® Peak Flow Meter Disposable Mouthpiece	200	49502-0201-01 49502-3070-70
Dey	Astech® Peak Flow Meter Adapter for Mouthpiece	12	49502-0202-12 49502-3070-75
Dey	Astech® Peak Flow Meter Disposable Mouthpiece	48	49502-0202-48 49502-0202-80
Dey	Astech® Peak Flow Meter Disposable Mouthpiece	500	49502-0202-99 49502-3070-85
Dey	Curosurf® (poractant alfa) 80mg/ml 1.5 ml	1	49502-0180-01
Dey	Curosurf® (poractant alfa) 80mg/ml 3.0 ml	1	49502-0180-03

Dey	DuoNeb® (ipratropium bromide 0.5mg/albuterol sulfate 3.0mg) Inhalation Solution 3ml	30	49502-0672-30
Dey	DuoNeb® (ipratropium bromide 0.5mg/albuterol sulfate 3.0mg) Inhalation Solution 3ml	60	49502-0672-60

Dey	EasiVent® Valved Holding Chamber	1	49502-0207-01
Dey	EasiVent® Valved Holding Chamber Hospital Pack	25	49502-0207-25
Dey	EasiVent® Mask – Small	1	49502-0208-01
Dey	EasiVent® Mask – Medium	1	49502-0208-02
Dey	EasiVent® Mask – Large	1	49502-0208-03

Dey	EpiPen® Auto-Injector (Epinephrine) 0.3mg	1	49502-0500-01
Dey	EpiPen® Jr. Auto-Injector (Epinephrine) 0.15mg	1	49502-0501-01
Dey	EpiPen® 2-Pak Auto-Injector (Epinephrine) 0.3mg	2	49502-0500-02
Dey	EpiPen® Jr. 2-Pak Auto-Injector (Epinephrine) 0.15mg	2	49502-0501-02
Dey	EpiPen® Trainer	1	49502-0500-00
Dey	Ipratropium Bromide Solution (Nasal Spray) 0.03% 30 ml	1	49502-0785-30
Dey	Ipratropium Bromide Solution (Nasal Spray) 0.06% 15 ml	1	49502-0786-15
Dey	Metaproterenol 0.40% 2.5 ml	25	49502-0678-03

Dey	Metaproterenol 0.60% 2.5 ml	25	49502-0676-03
Dey	Sodium Chloride 0.45% 3 ml	100	49502-0820-03 49502-0620-03
Dey	Sodium Chloride 0.45% 5 ml	100	49502-0820-05 49502-0620-05
Dey	Sodium Chloride 0.90% 3 ml	100	49502-0830-03 49502-0630-03

Dey	Sodium Chloride 0.90% 5 ml	100	49502-0830-05 49502-0630-05
Dey	Sodium Chloride 0.90%, 15 ml	50	49502-0830-50 49502-0630-15 (sic)
Dey	Sodium Chloride 3% 15 ml	50	49502-0640-15
Dey	Sodium Chloride 10% 15 ml	50	49502-0641-15
Dey	Sterile Water 3 ml	100	49502-0810-03 49502-0610-03
Dey	Sterile Water 5 ml	100	49502-0810-05 49502-0610-05
Dey	Isoetharine Inhalation Solution USP Sulfite-Free 0.08% 3 ml	25	49502-0661-03
Dey	Isoetharine Inhalation Solution USP Sulfite-Free 0.1% 5 ml	25	49502-0664-05
Dey	Isoetharine Inhalation Solution USP Sulfite-Free 0.17% 3 ml	25	49502-0660-03
Dey	Isoetharine Inhalation Solution USP Sulfite-Free 0.25% 2 ml	25	49502-0659-02
Dey	Atenolol Tablets USP 50 mg	100	49502-0400-01
Dey	Atenolol Tablets USP 100 mg	100	49502-0401-01
Dey	Piroxicam Tablets USP 20 mg	100	49502-0403-01
Dey	Alprazolam Tablets USP 0.25 mg	100	49502-0405-01
Dey	Alprazolam Tablets USP 0.25 mg	500	49502-0405-05
Dey	Alprazolam Tablets USP 0.5 mg	100	49502-0406-01
Dey	Alprazolam Tablets USP 0.5 mg	500	49502-0406-05
Dey	Alprazolam Tablets USP 1 mg	100	49502-0407-01
Dey	Alprazolam Tablets USP 1 mg	500	49502-0407-05
Dey	Pindolol Tablets USP 5 mg	100	49502-0409-01

Dey	Pindolol Tablets USP 10 mg	100	49502-0410-01
Dey	Triazolam Tablets USP 0.125 mg	100	49502-0412-01
Dey	Triazolam Tablets USP 0.25 mg	100	49502-0413-01
Dey	Hydrocodone Bitartrate 5 mg w/Acetaminophen USP 500 mg	100	49502-0415-01
Dey	Hydrocodone Bitartrate 5 mg w/Acetaminophen USP 500 mg	500	49502-0415-05
Dey	Hydrocodone Bitartrate 7.5 mg w/Acetaminophen USP 650 mg	100	49502-0417-01
Dey	Hydrocodone Bitartrate 7.5 mg w/Acetaminophen USP 750 mg	100	49502-0416-01
Dey	Theophylline (Anhydrous) USP Extended rls 100 mg	100	49502-0431-01
Dey	Theophylline (Anhydrous) USP Extended rls 200 mg	100	49502-0432-01
Dey	Theophylline (Anhydrous) USP Extended rls 200 mg	500	49502-0432-05
Dey	Theophylline (Anhydrous) USP Extended rls 300 mg	100	49502-0433-01
Dey	Theophylline (Anhydrous) USP Extended rls 300 mg	500	49502-0433-05
Dey	Theophylline (Anhydrous) USP Extended rls 300 mg	1000	49502-0433-10
Dey	Albuterol Sulfate Syrup 2 mg/5 ml 16 oz	1	49502-0795-16
Dey	Sodium Chloride 0.9% 3 ml	250	49502-0030-03
Dey	Sodium Chloride 0.9% 5 ml	250	49502-0030-05
Dey	Sodium Chloride 0.9% 10 ml	125	49502-0030-10
Dey	Sodium Chloride 0.9% 20 ml	100	49502-0030-20
Dey	Sodium Chloride Solution (Skin Wound Cleaner) 0.9% 220 ml	1	49502-0282-20

Dey	Sodium Chloride Solution (Nebusol) 0.9% 120 ml	6	49502-0501-20
Dey	Sodium Chloride Solution (Nebusol) 0.9% 300 ml	6	49502-0503-00
Dey	Sodium Chloride Solution (Dey- Pak®) 0.9% 1 ml	250	49502-0630-01
Dey	Sodium Chloride Solution (Dey- Pak®) 0.9% 10 ml	50	49502-0630-10
Dey	Sodium Chloride Solution (Dey- Pak®) 0.9% 15 ml	50	49502-0630-15
Dey	Sodium Chloride Solution 0.9% 3 ml	100	49502-0831-03
Dey	Sodium Chloride Solution 0.9% 5 ml	100	49502-0831-05
Dey	Sodium Chloride 0.90%, 15 ml	24	49502-0830-15
EM Pharma	Euthyrox (Levothyroxine Sodium Tabs USP) 25 mcg	100	63254-0435-01
EM Pharma	Euthyrox (Levothyroxine Sodium Tabs USP) 25 mcg	1000	63254-0435-10
EM Pharma	Euthyrox (Levothyroxine Sodium Tabs USP) 50 mcg	100	63254-0436-01
EM Pharma	Euthyrox (Levothyroxine Sodium Tabs USP) 50 mcg	1000	63254-0436-10
EM Pharma	Euthyrox (Levothyroxine Sodium Tabs USP) 75 mcg	100	63254-0437-01
EM Pharma	Euthyrox (Levothyroxine Sodium Tabs USP) 75 mcg	1000	63254-0437-10
EM Pharma	Euthyrox (Levothyroxine Sodium Tabs USP) 88 mcg	100	63254-0438-01
EM Pharma	Euthyrox (Levothyroxine Sodium Tabs USP) 88 mcg	1000	63254-0438-10
EM Pharma	Euthyrox (Levothyroxine Sodium Tabs USP) 100 mcg	100	63254-0439-01



EM Pharma	Euthyrox (Levothyroxine Sodium Tabs USP) 100 mcg	1000	63254-0439-10
EM Pharma	Euthyrox (Levothyroxine Sodium Tabs USP) 112 mcg	100	63254-0440-01
EM Pharma	Euthyrox (Levothyroxine Sodium Tabs USP) 112 mcg	1000	63254-0440-10
EM Pharma	Euthyrox (Levothyroxine Sodium Tabs USP) 125 mcg	100	63254-0441-01
EM Pharma	Euthyrox (Levothyroxine Sodium Tabs USP) 125 mcg	1000	63254-0441-10
EM Pharma	Euthyrox (Levothyroxine Sodium Tabs USP) 150 mcg	100	63254-0442-01
EM Pharma	Euthyrox (Levothyroxine Sodium Tabs USP) 150 mcg	1000	63254-0442-10
EM Pharma	Euthyrox (Levothyroxine Sodium Tabs USP) 175 mcg	100	63254-0443-01
EM Pharma	Euthyrox (Levothyroxine Sodium Tabs USP) 175 mcg	1000	63254-0443-10
EM Pharma	Euthyrox (Levothyroxine Sodium Tabs USP) 200 mcg	100	63254-0444-01
EM Pharma	Euthyrox (Levothyroxine Sodium Tabs USP) 200 mcg	1000	63254-0444-10
EM Pharma	Euthyrox (Levothyroxine Sodium Tabs USP) 300 mcg	100	63254-0445-01
EM Pharma	Euthyrox (Levothyroxine Sodium Tabs USP) 300 mcg	1000	63254-0445-10
Center Labs	EpiPen® Auto-Injector (Epinephrine) 0.3mg	1	00268-0301-01
Center Labs	EpiPen® Trainer	1	00268-0301-00
Center Labs	EpiPen® Jr. Auto-Injector (Epinephrine) 0.15mg	1	00268-0302-01

Center Labs	Epi EZPen® Auto-Injector w/Release Button & Trainer (Epinephrine) 0.3 mg	1	00268-0303-01
Center Labs	Epi EZPen® Jr. Auto-Injector w/Release Button & Trainer (Epinephrine) 0.15 mg	1	00268-0304-01

**SETTLEMENT AGREEMENT**

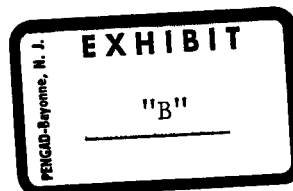
This Settlement Agreement ("Agreement") is entered by and between the (1) United States of America, acting through (a) its Department of Justice and (b) the United States Attorney's Office for the Southern District of Florida, and on behalf of the Office of Inspector General of the Department of Health and Human Services ("OIG-HHS"); (2) Dey L.P. and Dey, Inc. (collectively referred to as "Dey"); and (3) Ven-A-Care (the "Relator") (collectively referred to as "the Parties"), through their authorized representatives.

**PREAMBLE**

A. WHEREAS, this Agreement addresses the United States' interest in civil claims against Dey as set forth in the petitions filed in State of Texas ex rel. Ven-A-Care v. Dey Inc., et al., Cause No. GV 002327. Dey and the State of Texas and Ven-A-Care have entered into a Settlement Agreement and Release dated June 11, 2003 (the "Texas Settlement Agreement").

B. WHEREAS, the United States alleges that between September 1, 1995 through March 31, 2003, Dey knowingly made, directly and indirectly, false representations to the Texas Vendor Drug Program of prices and costs for certain of their inhalation and other drugs and thereby caused false and fraudulent claims to be submitted to and paid by the Texas Medicaid Program. The drugs covered by this Agreement are set forth in Exhibit A. Dey's conduct, as described in Paragraph B, is hereafter referred to as the "Covered Conduct."

C. WHEREAS, the United States contends that it has civil claims against Dey for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-3733, other federal statutes and/or common law doctrines, as specified in Paragraph 2 below. The United States also contends that it has certain administrative claims against Dey under the provisions for permissive exclusion from the Medicare, Medicaid and other federal health care programs, 42 U.S.C. § 1320a-7(b), and the provisions for civil monetary penalties, 42 U.S.C. § 1320a-7a, for the Covered Conduct.



D. WHEREAS, Dey denies all the claims and allegations in Paragraph B and denies that it has any liability or engaged in wrongful conduct in connection with the Covered Conduct.

E. WHEREAS, to avoid the delay, uncertainty, inconvenience and expense of protracted litigation of these claims, and as a result of a mutual desire to settle their disputes, the United States and Dey reach a full and final settlement as to the Covered Conduct, as set forth in this Agreement.

### **TERMS AND CONDITIONS**

NOW, THEREFORE, in reliance on the representations contained herein and in consideration of the mutual promises, covenants, and obligations in this Agreement and the Texas Settlement Agreement, and for good and valuable consideration, receipt of which is hereby acknowledged, the Parties agree as follows:

1. Dey agrees to pay to the United States the sum of nine million two hundred and seven thousand dollars (\$9,207,000), consistent with Paragraph III(2)(a)(5) of the Texas Settlement Agreement and as set forth below (the "Federal Settlement Amount"). This sum shall constitute a debt immediately due and owing to the United States on the effective date of this Agreement. The Federal Settlement Amount shall be paid by electronic funds transfer no later than seven business days after Dey receives written payment instructions from the United States. Dey shall pay simple interest at the rate of 6% per annum in an amount of one thousand five hundred and thirteen dollars and forty-eight cents (\$1,513.48) for each day following the effective date of this Agreement before complete payment of the Federal Settlement Amount is made.

2. Subject to the exceptions in Paragraph 3 below, in consideration of the obligations of Dey set forth in this Agreement and conditioned upon Dey's payment in full of the Federal Settlement Amount, the United States, on behalf of itself, and its officers, agents, agencies, and

departments, releases (a) Dey and its current and former directors, officers and employees, and (b) Merck KGaA, Merck Sante S.A.S., Merck S.A., EMD Pharmaceuticals, Inc. and EMD, Inc. (collectively, the "Merck Companies") and their current and former directors, officers and employees from any civil or administrative monetary claim that the United States has or may have under the False Claims Act, 31 U.S.C. §§ 3729-3733; the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-3812; the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a; and common law claims for fraud, payment by mistake, unjust enrichment, breach of contract or disgorgement for the Covered Conduct.

3. Notwithstanding any term of this Agreement, the United States specifically does not herein release any person or entity, including (i) Dey and its current and former directors, officers and employees and (ii) the Merck Companies and their current and former directors, officers and employees, from any and all of the following:

- (a) any criminal, civil or administrative claims arising under Title 26, U.S. Code (Internal Revenue Code);
- (b) any criminal liability;
- (c) any liability to the United States (or any agencies thereof) for any conduct other than the Covered Conduct;
- (d) any claims based upon obligations created by this Agreement;
- (e) any administrative liability other than that released in Paragraph 2 above;
- (f) any express or implied warranty claims or other claims for defective or deficient products and services provided by Dey;
- (g) any claims for personal injury or for related consequential damages arising from the Covered Conduct;
- (h) any claim based on a failure to deliver products or services due;

(i) any civil or administrative liability of individuals (including current or former directors, officers, and employees) who receive written notification that they are the target of a criminal investigation (as defined in the United States Attorneys' Manual), are indicted, charged, or convicted, or who enter into a plea agreement related to the Covered Conduct. To the extent, however, any such individuals are legally entitled to repayment from Dey, by claim for indemnification, contribution, reimbursement or otherwise as a result of a claim brought by the United States, the releases provided in Paragraph 2 above shall apply to such individuals with respect to that claim; or

(j) any claims arising from Dey's obligation to report prices or costs for the calculation of rebates and to pay rebates, under any law or contract, to the Centers for Medicare and Medicaid Services ("CMS") and the Texas Medicaid Program.

4. The OIG-HHS expressly reserves all rights to institute, direct, or maintain any administrative action seeking exclusion against Dey, its current and former directors, officers, and employees, the Merck Companies, and their current and former directors, officers and employees, from Medicare, Medicaid, or other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f) under 42 U.S.C. § 1320a-7(a) mandatory exclusion), or 42 U.S.C. § 1320a-7(b) (permissive exclusion).

5. Dey fully and finally releases the United States, its agencies, employees, servants, and agents from any claims (including attorneys' fees, costs, and expenses of every kind and however denominated) which Dey has asserted, could have asserted, or may assert in the future against the United States, its agencies, employees, servants, and agents, related to or arising from the Covered Conduct or the United States' investigation of the Covered Conduct up to the effective date of this Agreement. Should the Merck Companies ever assert any claim against the United States, its agencies, employees, servants, and agents related to or arising from the

Covered Conduct, however, then the release provided for in Paragraph 2 for the Merck Companies will be rendered null and void.

6. The Relator agrees that this Settlement Agreement is fair, adequate, and reasonable under all the circumstances, and agrees not to challenge this Agreement pursuant to 31 U.S.C. § 3730(c)(2)(B), and expressly waives the opportunity for a hearing on any objection to this Agreement pursuant to 31 U.S.C. § 3730(c)(2)(B). The Relator further agrees that this Agreement, and information relating to this Agreement, may be made public.

7. Upon the United States' receipt of Dey's payment of the Federal Settlement Amount, the Relator, for itself and its employees, servants, attorneys and agents, fully and finally releases, waives and forever discharges Dey, its former and current directors, officers and employees, the Merck Companies, and their current and former directors officers and employees from any claim that the Relator has or may have for the Covered Conduct. The Relator expressly does not release Dey, its former and current directors, officers and employees, and the Merck Companies, their current and former directors, officers and employees, for (a) any claims the Relator may have arising from Dey's obligations to report and/or to pay rebates to any State under contract or law; (b) any claims the Relator may have under any provision of 31 U.S.C.A. §§ 3729 -3733, except for claims related to any recovery attributable to the impact on Texas Medicaid of the Covered Conduct; or (c) any claims the Relator may have under the qui tam provisions of the laws of any state other than Texas.

8. The United States agrees to pay the Relator an amount of one million eight hundred forty-one thousand four hundred dollars (\$1,841,400) (the "Relator's share"), as Relator's share of the proceeds. Upon receipt of its Relator's share, the Relator, for itself, and its successors, agents, attorneys and assigns, and their successors, agents, attorneys, and assigns, fully and finally releases, waives, and forever discharges the United States from any claims pursuant to 31 U.S.C. § 3730, including 31 U.S.C. §§ 3730(b), (c), (d), and (d)(1), and any state

False Claims Acts, respectively, for a share of the Federal Settlement Amount; and in full settlement of its claims under this Agreement. The Relator expressly does not release the United States for any claims for a share of federal amounts recovered from (a) any claims the Relator may have arising from Dey's obligations to report and/or to pay rebates to any State under contract or law; (b) any claims the Relator may have under any provision of 31 U.S.C.A. §§ 3729 -3733, except for claims related to any recovery attributable to the impact on Texas Medicaid of the Covered Conduct; or (c) any claims the Relator may have under the qui tam provisions of the laws of any state other than Texas. This Agreement does not resolve or in any manner affect any claims the United States has or may have against the Relator arising under Title 26, U.S. Code (Internal Revenue Code), or any claims arising under this Agreement.

9. Dey fully and finally releases the Relator, its employees, servants, attorneys and agents from any claims (including attorneys' fees, costs, and expenses of every kind and however denominated) which Dey has asserted, could have asserted, or may assert in the future against the Relator, its employees, servants, attorneys and agents, related to the Covered Conduct or the United States' investigation of the Covered Conduct, up to the effective date of this Agreement. This provision is not intended to release any claims Dey may have against the Relator unrelated to conduct in Texas.

10. Dey waives and will not assert any defenses it may have to any criminal prosecution or administrative action relating to the Covered Conduct which defenses may be based on a contention that, under the Double Jeopardy Clause of the Fifth Amendment of the Constitution or Excessive Fines Clause of the Eighth Amendment of the Constitution, this Agreement bars a remedy sought in such criminal prosecution or administrative action. The parties agree that this Agreement is not punitive in purpose or effect.

11. Dey agrees to the following:

(a) Unallowable Costs Defined: that all costs (as defined in the Federal



Acquisition Regulations (FAR) 48 C.F.R. § 31.205-47 and in Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§ 1395-1395ggg and 1396-1396v, and the regulations and official program directives promulgated thereunder) incurred by or on behalf of Dey, its present or former officers, directors, employees, shareholders, and agents in connection with: (1) the matters covered by this Agreement; (2) the United States' audit and civil investigation of the matters covered by this Agreement; (3) Dey's investigation, defense, and any corrective actions undertaken in response to the United States' audit and civil investigation in connection with the matters covered by this Agreement (including attorney's fees); (4) the negotiation and performance of this Agreement; and (5) the payment Dey makes to the United States pursuant to this Agreement are unallowable costs on Government contracts and under the Medicare Program, Medicaid Program, Railroad Retirement, TRICARE, DOD, and Federal Employees Health Benefits Program (FEHBP). However, nothing in this paragraph affects the status of costs that are not allowable based on any other authority applicable to Dey. (All costs described or set forth in this Paragraph 10(a) are hereafter, "unallowable costs").

(b) Future Treatment of Unallowable Costs: If applicable, these unallowable costs will be separately estimated and accounted for by Dey, and Dey will not charge such unallowable costs directly or indirectly to any contracts with the United States or any state Medicaid Program, or seek payment for such unallowable costs through any cost report, cost statement, information statement, or payment request submitted by Dey or any of its subsidiaries to the Medicare, Medicaid, TRICARE, DOD, Railroad Retirement or FEHBP Programs.

(c) Treatment of Unallowable Costs Previously Submitted for Payment: If applicable, Dey further agrees that within 60 days of the effective date of this Agreement, it will identify to applicable Medicare, Railroad Retirement and TRICARE fiscal intermediaries, carriers, and/or contractors, and Medicaid, DOD, VA and FEHBP fiscal agents, any unallowable costs (as defined in this Paragraph) included in payments previously sought from the United

States, the Texas Medicaid Program, or any state Medicaid program, including, but not limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by Dey or any of its subsidiaries, and will request, and agree, that such cost reports, cost statements, information reports, or payment requests, even if already settled, be adjusted to account for the effect of the inclusion of the unallowable costs. Dey agrees that the United States, at a minimum, will be entitled to recoup from Dey any overpayment plus applicable interest as a result of the inclusion of such unallowable costs on previously-submitted cost reports, information reports, cost statements, or requests for payment. Any payment due after the adjustments have been made shall be paid to the United States pursuant to the direction of the Department of Justice, and/or the affected agencies. The United States reserves its rights to disagree with any calculations submitted by Dey or any of its subsidiaries on the effect of inclusion of unallowable costs (as defined in this Paragraph) on Dey or any of its subsidiaries' cost reports, cost statements, or information reports. Nothing in this Agreement shall constitute a waiver of the rights of the United States to examine or reexamine the unallowable costs described in this Paragraph.

12. If applicable, Dey agrees that it will not seek payment for any of the health care billings covered by this Agreement from any health care beneficiaries or their parents or sponsors. Dey waives any causes of action against these beneficiaries or their parents or sponsors based upon the claims for payment covered by this Agreement.

13. Dey expressly warrants that it has reviewed its financial situation and that it currently is solvent within the meaning of 11 U.S.C. §§ 547(b)(3) and 548(a)(1)(A)(ii)(I), and will remain solvent following its payment to the United States hereunder. Further, the Parties expressly warrant that, in evaluating whether to execute this Agreement, the Parties (i) have intended that the mutual promises, covenants and obligations set forth herein constitute a contemporaneous exchange for new value given to Dey, within the meaning of 11 U.S.C. §

547(c)(1), and (2) have concluded that these mutual promises, covenants and obligations do, in fact, constitute such a contemporaneous exchange.

14. This Agreement is intended to be only for the benefit of the Parties and the persons and entities released by the Agreement, and by this instrument the Parties do not release any claims against any other person or entity.

15. Nothing in any provision of this Agreement constitutes an agreement by the United States concerning the characterization of the Federal Settlement Amount for purposes of the Internal Revenue Laws, Title 26 of the United States Code.

16. Each party to this Agreement will bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

17. Dey represents that this Agreement is freely and voluntarily entered into without any degree of duress or compulsion whatsoever.

18. This Agreement is governed by the laws of the United States. The Parties agree that the exclusive jurisdiction and venue for any dispute arising between and among the Parties under this Agreement will be the United States District Court for the Southern District of Florida.

19. The undersigned signatory represents and warrants that he is authorized by Dey to execute this Agreement. The undersigned United States signatories represent that they are signing this Agreement in their official capacities and they are authorized to execute this Agreement on behalf of the United States through their respective agencies and departments.

20. The effective date of this Agreement shall be the date of signature of the last signatory to the Agreement.

21. This Agreement shall be binding on all successors, transferees, heirs and assigns of the Parties.

22. This Agreement constitutes the complete agreement between the Parties with regard to the Covered Conduct. This Agreement may not be amended except by written consent of the Parties.

23. This Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same agreement.

24. The Parties agree that this Agreement does not constitute an admission of fault or liability by Dey. The Parties also agree that this Agreement does not constitute evidence of any liability or unlawful conduct on the part of Dey (although it may be used or relied upon for purposes other than as evidence of liability or unlawful conduct, such as demonstrating the fact of a settlement). The Parties further agree that this Agreement is not a concession by the United States that its claims are not well founded.

**UNITED STATES OF AMERICA**

**DEY, INC. and  
DEY L.P.**

By: \_\_\_\_\_

By: \_\_\_\_\_

Date: \_\_\_\_\_

Date: \_\_\_\_\_

Printed Name: Laurie A. Oberembt

Printed Name: \_\_\_\_\_

Trial Attorney  
Commercial Litigation Branch  
Civil Division  
United States Department of Justice

Title: \_\_\_\_\_

**UNITED STATES DEPARTMENT OF  
HEALTH AND HUMAN SERVICES'  
OFFICE OF INSPECTOR GENERAL**

By: \_\_\_\_\_

Date: \_\_\_\_\_

Printed Name: Larry J. Goldberg

Assistant Inspector General for Legal Affairs  
Office of Counsel to the Inspector General  
Office of Inspector General  
United States Department of Health and  
Human Services

**Relator, Ven-a-Care of the Florida Keys,  
Inc.**

**Relator, Ven-a-Care of the Florida Keys,  
Inc.**

By: \_\_\_\_\_

By: \_\_\_\_\_

Date: \_\_\_\_\_

Date: \_\_\_\_\_

Printed Name: James J. Breen, Esq.

Printed Name: Zachary Bentley

The Breen Law Firm, P.A.

Title: \_\_\_\_\_

**EXHIBIT A**

Dey	Albuterol Sulfate Inhalation Solution .083% 3ml	25	49502-0697-03
Dey	Albuterol Sulfate Inhalation Solution .083% 3ml	30	49502-0697-33
Dey	Albuterol Sulfate Inhalation Solution .083% 3 ml	60	49502-0697-60
Dey	Albuterol Sulfate Concentrate Solution 0.5% 20 ml	1	49502-0105-01 49502-0196-20
Dey	Acetylcysteine Solution 10% 4 ml	12	49502-0181-04
Dey	Acetylcysteine Solution 10% 10 ml	3	49502-0181-10
Dey	Acetylcysteine Solution 10% 30ml	3	49502-0181-30
Dey	Acetylcysteine Solution 20% 4 ml	12	49502-0182-04
Dey	Acetylcysteine Solution 20% 10 ml	3	49502-0182-10
Dey	Acetylcysteine Solution 20% 30 ml	3	49502-0182-30
Dey	Acetylcysteine Solution 20% 100 ml	1	49502-0182-00

Dey	Cromolyn Sodium Inhalation Solution USP 20mg 2ml	60	49502-0689-02
Dey	Cromolyn Sodium Inhalation Solution USP 20mg 2ml	120	49502-0689-12
Dey	Ipratropium Bromide 0.02% 2.5ml	25	49502-0685-03
Dey	Ipratropium Bromide 0.02% 2.5ml	30	49502-0685-33
Dey	Ipratropium Bromide 0.02% 2.5ml	60	49502-0685-60
Dey	Albuterol Aerosol Inhaler Kit 90mcg 17 gm	1	49502-0333-17 49502-0303-17
Dey	Albuterol Aerosol Inhaler Refill 90mcg 17 gm	1	49502-0303-27 49502-0333-27
Dey	AccuNeb® (albuterol sulfate) Inhalation Solution 0.63 mg 3 ml	25	49502-0692-03
Dey	AccuNeb® (albuterol sulfate) Inhalation Solution 1.25 mg 3 ml	25	49502-0693-03
Dey	Ace® Holding Chamber	1	49502-0203-01 49502-3080-10
Dey	Ace® Holding Chamber Hospital Pack	25	49502-3080-25
Dey	Ace® Plastic Adapters	5	49502-3080-60

Dey	Astech® Peak Flow Meter	1	49502-0200-01 49502-3070-10
Dey	Astech® Peak Flow Meter Hospital Pack	25	49502-0200-99 49502-3070-25
Dey	Astech® Peak Flow Meter Disposable Mouthpiece	200	49502-0201-01 49502-3070-70
Dey	Astech® Peak Flow Meter Adapter for Mouthpiece	12	49502-0202-12 49502-3070-75
Dey	Astech® Peak Flow Meter Disposable Mouthpiece	48	49502-0202-48 49502-0202-80
Dey	Astech® Peak Flow Meter Disposable Mouthpiece	500	49502-0202-99 49502-3070-85
Dey	Curosurf® (poractant alfa) 80mg/ml 1.5 ml	1	49502-0180-01
Dey	Curosurf® (poractant alfa) 80mg/ml 3.0 ml	1	49502-0180-03
Dey	DuoNeb® (ipratropium bromide 0.5mg/albuterol sulfate 3.0mg) Inhalation Solution 3ml	30	49502-0672-30
Dey	DuoNeb® (ipratropium bromide 0.5mg/albuterol sulfate 3.0mg) Inhalation Solution 3ml	60	49502-0672-60
Dey	EasiVent® Valved Holding Chamber	1	49502-0207-01



Dey	EasiVent® Valved Holding Chamber Hospital Pack	25	49502-0207-25
Dey	EasiVent® Mask – Small	1	49502-0208-01
Dey	EasiVent® Mask – Medium	1	49502-0208-02
Dey	EasiVent® Mask – Large	1	49502-0208-03
Dey	EpiPen® Auto-Injector (Epinephrine) 0.3mg	1	49502-0500-01
Dey	EpiPen® Jr. Auto-Injector (Epinephrine) 0.15mg	1	49502-0501-01
Dey	EpiPen® 2-Pak Auto-Injector (Epinephrine) 0.3mg	2	49502-0500-02
Dey	EpiPen® Jr. 2-Pak Auto-Injector (Epinephrine) 0.15mg	2	49502-0501-02
Dey	EpiPen® Trainer	1	49502-0500-00
Dey	Ipratropium Bromide Solution (Nasal Spray) 0.03% 30 ml	1	49502-0785-30
Dey	Ipratropium Bromide Solution (Nasal Spray) 0.06% 15 ml	1	49502-0786-15
Dey	Metaproterenol 0.40% 2.5 ml	25	49502-0678-03

Dey	Metaproterenol 0.60% 2.5 ml	25	49502-0676-03
Dey	Sodium Chloride 0.45% 3 ml	100	49502-0820-03 49502-0620-03
Dey	Sodium Chloride 0.45% 5 ml	100	49502-0820-05 49502-0620-05
Dey	Sodium Chloride 0.90% 3 ml	100	49502-0830-03 49502-0630-03
Dey	Sodium Chloride 0.90% 5 ml	100	49502-0830-05 49502-0630-05
Dey	Sodium Chloride 0.90%, 15 ml	50	49502-0830-50 49502-0630-15 (sic)
Dey	Sodium Chloride 3% 15 ml	50	49502-0640-15
Dey	Sodium Chloride 10% 15 ml	50	49502-0641-15
Dey	Sterile Water 3 ml	100	49502-0810-03 49502-0610-03
Dey	Sterile Water 5 ml	100	49502-0810-05 49502-0610-05

Dey	Isoetharine Inhalation Solution USP Sulfite-Free 0.08% 3 ml	25	49502-0661-03
Dey	Isoetharine Inhalation Solution USP Sulfite-Free 0.1% 5 ml	25	49502-0664-05
Dey	Isoetharine Inhalation Solution USP Sulfite-Free 0.17% 3 ml	25	49502-0660-03
Dey	Isoetharine Inhalation Solution USP Sulfite-Free 0.25% 2 ml	25	49502-0659-02
Dey	Atenolol Tablets USP 50 mg	100	49502-0400-01
Dey	Atenolol Tablets USP 100 mg	100	49502-0401-01
Dey	Piroxicam Tablets USP 20 mg	100	49502-0403-01
Dey	Alprazolam Tablets USP 0.25 mg	100	49502-0405-01
Dey	Alprazolam Tablets USP 0.25 mg	500	49502-0405-05
Dey	Alprazolam Tablets USP 0.5 mg	100	49502-0406-01
Dey	Alprazolam Tablets USP 0.5 mg	500	49502-0406-05
Dey	Alprazolam Tablets USP 1 mg	100	49502-0407-01
Dey	Alprazolam Tablets USP 1 mg	500	49502-0407-05

Dey	Pindolol Tablets USP 5 mg	100	49502-0409-01
Dey	Pindolol Tablets USP 10 mg	100	49502-0410-01
Dey	Triazolam Tablets USP 0.125 mg	100	49502-0412-01
Dey	Triazolam Tablets USP 0.25 mg	100	49502-0413-01
Dey	Hydrocodone Bitartrate 5 mg w/Acetaminophen USP 500 mg	100	49502-0415-01
Dey	Hydrocodone Bitartrate 5 mg w/Acetaminophen USP 500 mg	500	49502-0415-05
Dey	Hydrocodone Bitartrate 7.5 mg w/Acetaminophen USP 650 mg	100	49502-0417-01
Dey	Hydrocodone Bitartrate 7.5 mg w/Acetaminophen USP 750 mg	100	49502-0416-01
Dey	Theophylline (Anhydrous) USP Extended rls 100 mg	100	49502-0431-01
Dey	Theophylline (Anhydrous) USP Extended rls 200 mg	100	49502-0432-01
Dey	Theophylline (Anhydrous) USP Extended rls 200 mg	500	49502-0432-05
Dey	Theophylline (Anhydrous) USP Extended rls 300 mg	100	49502-0433-01

Dey	Theophylline (Anhydrous) USP Extended rls 300 mg	500	49502-0433-05
Dey	Theophylline (Anhydrous) USP Extended rls 300 mg	1000	49502-0433-10
Dey	Albuterol Sulfate Syrup 2 mg/5 ml 16 oz	1	49502-0795-16
Dey	Sodium Chloride 0.9% 3 ml	250	49502-0030-03
Dey	Sodium Chloride 0.9% 5 ml	250	49502-0030-05
Dey	Sodium Chloride 0.9% 10 ml	125	49502-0030-10
Dey	Sodium Chloride 0.9% 20 ml	100	49502-0030-20
Dey	Sodium Chloride Solution (Skin Wound Cleaner) 0.9% 220 ml	1	49502-0282-20
Dey	Sodium Chloride Solution (Nebusol) 0.9% 120 ml	6	49502-0501-20
Dey	Sodium Chloride Solution (Nebusol) 0.9% 300 ml	6	49502-0503-00
Dey	Sodium Chloride Solution (Dey- Pak®) 0.9% 1 ml	250	49502-0630-01
Dey	Sodium Chloride Solution (Dey- Pak®) 0.9% 10 ml	50	49502-0630-10

Dey	Sodium Chloride Solution (Dey-Pak®) 0.9% 15 ml	50	49502-0630-15
Dey	Sodium Chloride Solution 0.9% 3 ml	100	49502-0831-03
Dey	Sodium Chloride Solution 0.9% 5 ml	100	49502-0831-05
Dey	Sodium Chloride 0.90%, 15 ml	24	49502-0830-15
EM Pharma	Euthyrox (Levothyroxine Sodium Tabs USP) 25 mcg	100	63254-0435-01
EM Pharma	Euthyrox (Levothyroxine Sodium Tabs USP) 25 mcg	1000	63254-0435-10
EM Pharma	Euthyrox (Levothyroxine Sodium Tabs USP) 50 mcg	100	63254-0436-01
EM Pharma	Euthyrox (Levothyroxine Sodium Tabs USP) 50 mcg	1000	63254-0436-10
EM Pharma	Euthyrox (Levothyroxine Sodium Tabs USP) 75 mcg	100	63254-0437-01
EM Pharma	Euthyrox (Levothyroxine Sodium Tabs USP) 75 mcg	1000	63254-0437-10
EM Pharma	Euthyrox (Levothyroxine Sodium Tabs USP) 88 mcg	100	63254-0438-01

EM Pharma	Euthyrox (Levothyroxine Sodium Tabs USP) 88 mcg	1000	63254-0438-10
EM Pharma	Euthyrox (Levothyroxine Sodium Tabs USP) 100 mcg	100	63254-0439-01
EM Pharma	Euthyrox (Levothyroxine Sodium Tabs USP) 100 mcg	1000	63254-0439-10
EM Pharma	Euthyrox (Levothyroxine Sodium Tabs USP) 112 mcg	100	63254-0440-01
EM Pharma	Euthyrox (Levothyroxine Sodium Tabs USP) 112 mcg	1000	63254-0440-10
EM Pharma	Euthyrox (Levothyroxine Sodium Tabs USP) 125 mcg	100	63254-0441-01
EM Pharma	Euthyrox (Levothyroxine Sodium Tabs USP) 125 mcg	1000	63254-0441-10
EM Pharma	Euthyrox (Levothyroxine Sodium Tabs USP) 150 mcg	100	63254-0442-01
EM Pharma	Euthyrox (Levothyroxine Sodium Tabs USP) 150 mcg	1000	63254-0442-10
EM Pharma	Euthyrox (Levothyroxine Sodium Tabs USP) 175 mcg	100	63254-0443-01
EM Pharma	Euthyrox (Levothyroxine Sodium Tabs USP) 175 mcg	1000	63254-0443-10

EM Pharma	Euthyrox (Levothyroxine Sodium Tabs USP) 200 mcg	100	63254-0444-01
EM Pharma	Euthyrox (Levothyroxine Sodium Tabs USP) 200 mcg	1000	63254-0444-10
EM Pharma	Euthyrox (Levothyroxine Sodium Tabs USP) 300 mcg	100	63254-0445-01
EM Pharma	Euthyrox (Levothyroxine Sodium Tabs USP) 300 mcg	1000	63254-0445-10
Center Labs	EpiPen® Auto-Injector (Epinephrine) 0.3mg	1	00268-0301-01
Center Labs	EpiPen® Trainer	1	00268-0301-00
Center Labs	EpiPen® Jr. Auto-Injector (Epinephrine) 0.15mg	1	00268-0302-01
Center Labs	Epi EZPen® Auto-Injector w/Release Button & Trainer (Epinephrine) 0.3 mg	1	00268-0303-01
Center Labs	Epi EZPen® Jr. Auto-Injector w/Release Button & Trainer (Epinephrine) 0.15 mg	1	00268-0304-01





parties as expressed in their Settlement Agreement. The Merck Defendants, having challenged personal jurisdiction, have not joined in this Motion, although their dismissal is contemplated by and essential to the settlement.

Respectfully submitted,

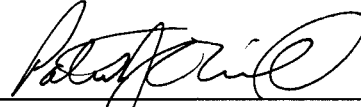
Fleckman & McGlynn, PLLC  
515 Congress Avenue, Suite 1800  
Austin, Texas 78701-3503  
Telephone: (512) 476-7900  
Facsimile: (512) 476-7644

A handwritten signature in black ink, appearing to read "Steven A. Fleckman", is written over a horizontal line.

Steven A. Fleckman  
State Bar No. 07118300  
Jessica M. McGlynn  
State Bar No. 13637410  
Julia B. Kenner  
State Bar No. 02008355

Attorneys for Defendants Dey, Inc.,  
Dey, L.P., A Limited Partnership,  
Merck Sante S.A.S., Merck S.A.,  
Merck, KGaA, and EMD, Inc.

Office of Attorney General  
Elder Law and Public Health Division  
P.O. Box 12548  
Austin, TX 78711-2548  
Telephone: (512) 475-4193  
Facsimile: (512) 499-0712

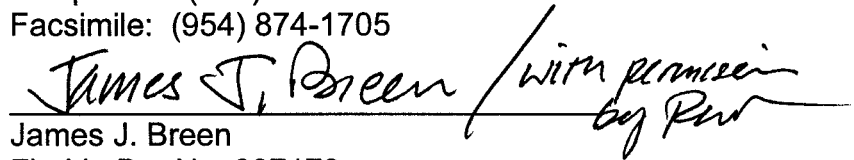


---

Patrick J. O'Connell  
State Bar No. 15179900

Attorney for The State of Texas

The Breen Law Firm, P.A.  
P.O. Box 297470  
Pembroke Pines, Florida  
Telephone: (954) 874-1635  
Facsimile: (954) 874-1705



---

James J. Breen  
Florida Bar No. 297178  
Alison W. Simon  
Florida Bar No. 0109568

Attorneys for Ven-A Care  
of the Florida Keys, Inc.



hereby taxed against the party incurring same. This Court makes no finding, and by entering this Order has made no finding, as to the existence of personal jurisdiction over Merck Sante S.A.S., Merck S.A., Merck KGaA, or EMD, Inc., each of which entities has denied the existence of such jurisdiction, and none of whom have sought any relief granted herein. It is further

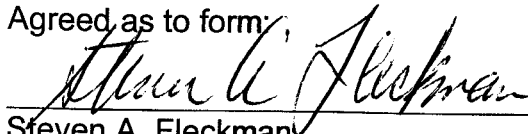
ORDERED, that the Court's Amended Protective Order dated October 9, 2002, shall remain in effect as to all parties identified herein in accordance with its terms, as same may hereafter be modified in accordance with paragraph 14 thereof.

Signed this \_\_\_\_\_ day of \_\_\_\_\_, 2003.

---

JUDGE PRESIDING

Agreed, as to form:



Steven A. Fleckman

State Bar No. 07118300

Jessica M. McGlynn

State Bar No. 13637410

Julia B. Kenner

State Bar No. 02008355

Fleckman & McGlynn, PLLC

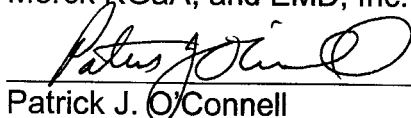
515 Congress Avenue, Suite 1800

Austin, Texas 78701-3503

Telephone: (512) 476-7900

Facsimile: (512) 476-7644

Attorneys for Defendants Dey, Inc.,  
Dey, L.P., A Limited Partnership,  
Merck Sante S.A.S., Merck S.A.,  
Merck KGaA, and EMD, Inc.



Patrick J. O'Connell

State Bar No. 15179900

Office of Attorney General

Elder Law and Public Health Division

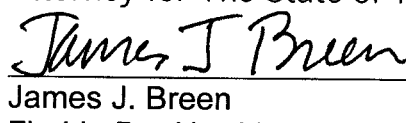
P.O. Box 12548

Austin, TX 78711-2548

Telephone: (512) 475-4193

Facsimile: (512) 499-0712

Attorney for The State of Texas

 / with permission  
by PCW

James J. Breen

Florida Bar No. 297178

Alison W. Simon

Florida Bar No. 0109568

The Breen Law Firm, P.A.

P.O. Box 297470

Pembroke Pines, Florida 33029-747-

Telephone: (954) 874-1635

Facsimile: (954) 874-1705

Attorneys for Ven-A-Care of the Florida Keys, Inc.